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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,689	08/05/2003	Yong Moon Choi	098390-34217A	7580

26345 7590 07/28/2005

GIBBONS, DEL DEO, DOLAN, GRIFFINGER & VECCHIONE  
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NEWARK, NJ 07102-5497

EXAMINER
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CHANNAVAJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/634,689

Applicant(s)

CHOI ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☒ Claim(s) 6-8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3-7-05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt of response and terminal disclaimer dated 9-2-04 and IDS dated 3-7-05 is acknowledged.

Claims 1-8 are pending.

The following rejection of record has been maintained:

Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-10 of U.S. Patent No. 6,627,211. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims a method of administering an anticonvulsive agent to the nasal membranes of a mammal and employs the same composition as that claimed in the instant application i.e., an anticonvulsive agent, an aqueous vehicle comprising 30-60% aliphatic alcohol, 30-60% glycol, a surfactant selected from bile salts and lecithin. Accordingly, instant composition is anticipated by the patented claims.

### ***Claim Rejections - 35 USC § 103***

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,428,006 to Bechgaard et al (Bechgaard).

Instant claim 1 is directed to a pharmaceutical composition comprising an anticonvulsive agent and an aqueous vehicle containing 30-60% aliphatic alcohol, 30-60% glycol and 0.1-5% bile salt or lecithin; and about 10% by volume of water. Dependent claims recite various amounts of the carrier components or specific anti-convulsive agents.

Bechgaard teaches nasal administration of active substances for rapid absorption of the substance into the blood stream, without causing unacceptable damage to the mucosal

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membrane. The composition of Bechgaard comprises active substances including anti-epileptic or anti-spasmodic agents such as clonazepam, diazepam etc (col. 4, lines 38-40). Bechgaard recognizes alcohol, glycol and glycol ether as well known carriers for nasal administration of hypnotics (col. 3, lines 26-32) and teaches a carrier or vehicle for the active agent, which comprises n-glycofurol and n-ethylene glycol containing 1-14 ethylene units (col.3, lines 52-67 and col.4, lines 1-9).

Bechgaard does not specifically teach the claimed proportions of aliphatic alcohol, glycol, water and bile salts or lecithin. However, Beechgaard teaches that the composition preferably comprises polyethylene glycol having a molecular weight between 200 and 750 and (col. 7, lines 40-60). Further, Bechgaard suggests incorporating one or more of surfactants and absorption promoters, such as bile salts or their derivatives, lecithin & lysolecithin; solvents, such as alcohol and other excipients in the formulation. Bechgaard also fails to teach the specific anticonvulsive agent of claim 3. However, Bechgaard addresses the same problem of achieving a rapid onset and a high plasma level of the medicament as that of the instant invention, and in particular for nasal administration of highly lipophilic substances such as benzodiazepines, in a total volume for as low as 1 micron. Accordingly, it would have been obvious for a skilled artisan at the time of the instant invention to add alcohols and surfactants (bile salts or lecithin), to the carrier vehicle of Bechgaard containing glycols, for nasal administration of anticonvulsive substances, because Bechgaard suggests that the alcohols increase solubility and surfactants enhance the absorption of these highly lipophilic substances and thus result in a controlled release formulations with a rapid onset of high plasma concentrations. Further, optimizing the amounts of the carriers such as water, alcohol and glycol, with an expectation to achieve the

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desired absorption of the drug is within the scope of a skilled artisan. Although Bechgaard does not teach anticonvulsive agent of claim 4, Bechgaard teaches in general anti-epileptic and anti-spasmolytic agents are suitable for nasal administration in their method. Accordingly, a skilled artisan would have been able to employ any anticonvulsive agent and yet achieved the same rapid onset of high plasma concentrations as taught by Bechgaard.

***Response to Arguments***

Applicant's arguments filed 9-2-04 have been fully considered but they are not persuasive.

Double patenting rejection: The terminal disclaimer filed on 9-2-04 has been received but has not been approved because of the absence of ownership clause. Accordingly, the rejection has been maintained.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,428,006 to Bechgaard et al (Bechgaard).

RESPONSE: Applicants argue that the superior results of the present invention are not taught or suggested by the prior art and that absent present disclosure there is no motivation and direction to prepare instant composition. Applicants admit that the Beechgaard teaches alcohol, glycol and glycol ether for the same purpose as that of the instant invention and yet argue that the reference teaches a narrow group of glycol ethers and there is no suggestion that the composition with n-glycofurol is suitable. Applicants' arguments are not persuasive because instant comprising language allows for n-glycofurol of Beechgaard. Further, unlike applicants' argument, Beechgaard particularly, teaches the claimed compounds i.e., diazepam, clonazepam etc and

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further teaches the polyethylene glycols of the claimed molecular weight. With respect to the “aqueous versus no-aqueous formulation”, Beechgaard teaches ‘substantially non-aqueous’ thus allowing minor amounts of water. Applicants’ have not provided any unexpected advantage of including 10% water in the instant composition, nor have shown that the “substantially non-aqueous” formulation of Beechgaard includes lower than the 10% claimed. Applicants argue that addition of 10% water increases the transnasal permeation rate by 8-fold. However, except claim 6, instant claims are not limited to diazepam and thus, the results are specific to diazepam.

#### ***Allowable Subject Matter***

Claims 6-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
July 25, 2005

  
THURMAN K. PAGE  
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